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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,811	07/23/2003	Anthony David Auffret	PC25042A	2538

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,811

Applicant(s)

AUFFRET ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 14-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/20/04 & 5/23/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the amendments filed on 05/23/05 in which a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15.

The response has the following effect:

1. Claims 1-13, the invention of Group I is prosecuted by the examiner. Claims 4-7, 11-14, 20, 23, 24, and 27-29 have been amended. Claims 14-29 are withdrawn.
2. The responsive is contained herein below.

Claims 1-29 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (DE 2737947, Abstract Only).

In claim 1, applicant claims “A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting;

(b) casting said composition into the shape of a dosage form; and

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(c) drying said dosage form under such conditions as to provide a form which rapidly dissolves and disperses in the mouth of the consumer.”

Mori et al. disclose applicant's process for preparing a film comprising pullulan and sodium alginate, which process comprises (a) preparing a solution polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting; (b) casting said composition into the shape of a film (a dosage form); and (c) drying said film (dosage form) (see abstract). It should be noted that although Mori et al. is silent about the properties or characteristics of the form which pertains to its ability to rapidly dissolve and disperse in the mouth of a consumer, Mori et al.'s composition is the same as applicant's composition (which also comprises pullulan and sodium alginate) and is prepared by the same method, and consequently should inherently possess the same properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (WO 00/18365).

In claim 1, applicant claims “A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan and sodium alginate

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having a viscosity suitable for casting;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form under such conditions as to provide a form which rapidly

dissolves and disperses in the mouth of the consumer.” Dependent claims 2-6 are

drawn to said method wherein the composition also comprises one or more pharmaceutically active agents and the composition is adjusted to specific pH range with specific acids. Dependent claim 8 is drawn to the process of claim 1 wherein the composition also contains one or both of the enzymes pullulanase and alginate lyase. Dependent claims 9 and 10 are drawn to the process of claim 1 wherein the composition or dosage form is irradiated with gamma-radiation at specific amounts. Dependent claim 11 is drawn to said method dissolved solution has specific viscosity. Dependent claims 12 and 13 are drawn to said method wherein drying (step c) is carried out at specific temperature range for specific times periods.

Leung et al. disclose a process for preparing a physiologically consumable film (a dosage form), which process comprises the

(a) preparing a hydrated polymer composition comprising pullulan
suitable for casting;

(b) casting said composition into the shape of a film (dosage form); and

(c) drying said dosage form to provide a form which dissolves and in the mouth of a consumer (see examples, page 31, line 11 to page 31, line 12; see also claims 18, 29 and 30). In addition, Leung et al. disclose that their composition can contain mixtures of water soluble film formers such as pullulan and sodium alginate (see claim 29).

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The difference between the applicant's claimed method and the method of Leung et al. is that Leung et al. do not specifically exemplify the use of sodium alginate together with pullulan in their preparation. However, Leung et al. disclose that their composition can contain mixtures of the water soluble film formers, pullulan and sodium alginate (see claim 29).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film.

One having ordinary skill in the art would have been motivated to have the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film. Dependent claims 2-6 which are drawn to said method wherein the composition also comprises one or more pharmaceutically active agents and the composition is adjusted to specific pH range with specific acids including aspartame, are also encompassed by this rejection since Leung et al. disclose the use of a pharmaceutically active agent (an antimicrobial) in the composition and disclose the use the aspartame in the composition (see claims and table 2, page 36). Furthermore, although Leung et al. do not disclose the pH of their composition, the adjustment of the pH is a matter of choice and does not appear to affect the composition formed. Dependent claim 8 which is drawn to the process of claim 1 wherein the composition also contains one or both of the enzymes pullulanase and alginate lyase, is also rejected as been obvious over Mori et al., since it is common and obvious to use or add enzymes

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that specifically catalyze the breakdown of substrates (such as pullulan and alginate) that are constituents of consumable compositions as to facilitate the digestion of said substrates.

Dependent claims 9 and 10 which is drawn to the process of claim 1 wherein the composition or dosage form is irradiated with gamma-radiation at specific amounts, are also rejected as being obvious over Mori et al., since gamma irradiation is commonly applied in processing or sterilization of foods, consumables and the like.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are not found convincing.

The applicant argues that Mori et al. process is clearly not intended for the preparation of films for oral consumption. However, Mori et al. film is prepared comprising the same ingredients as applicant's composition (pullulan and sodium alginate). Mori et al. composition, like applicant's composition, is also casted and dried. Consequently, Mori et al. composition has a viscosity suitable for casting, since their composition (like applicant's composition) is also casted. Furthermore, although Mori et al. does not disclose that their films are intended for oral consumption, Mori et al. prepared film comprises the same ingredients as applicant's composition (pullulan and sodium alginate) and is not disclosed as having any physical characteristics such as quantity, size or weight that distinguishes it from applicant's film composition. Thus, Mori et al. composition should also rapidly dissolve and disperse in the mouth. In fact, Mori et al. composition is a composition that can be orally consumed, since both pullulan and sodium alginate are well known edible compounds.

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The applicant argues that while the composition of Leung et al. contains pullulan and sodium alginate, such composition does not undergo the vital third step of the present invention by which the viscosity of the cast composition is reduced to achieve rapid oral uptake. However, applicant's does not recite in the claims nor claim that the viscosity of the cast composition is reduced, in the third step of the invention (see claims).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

August 5, 2005


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600